

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK A/S,

Plaintiff and Counterdefendant,

v.

AVENTIS PHARMACEUTICALS INC,
SANOFI-AVENTIS, and AVENTIS
PHARMA DEUTSCHLAND GMBH

Defendants and Counterplaintiffs.

C. A. No. 05-645-SLR

REDACTED - PUBLIC VERSION

**NOVO NORDISK A/S' MOTION TO VOLUNTARILY
DISMISS THE COMPLAINT AND TO DISMISS DEFENDANTS'
COUNTERCLAIMS FOR LACK OF SUBJECT MATTER JURISDICTION**

Plaintiff Novo Nordisk A/S ("Novo Nordisk"), by its attorneys White & Case LLP and Richards, Layton & Finger, P.A., hereby moves the Court for an order dismissing this action for lack of subject matter jurisdiction because the covenant not to sue (Exhibit A) that Novo Nordisk hereby provides Defendants Aventis Pharmaceuticals Inc., sanofi-aventis, and Aventis Pharma Deutschland GmbH's (hereinafter referred to collectively as "sanofi-aventis" or "Defendants") removes the controversy between the parties and has mooted this case.

BACKGROUND

This is an action for patent infringement, scheduled for a nine day trial beginning August 13, 2007. Novo Nordisk filed its Complaint on September 2, 2005, and alleged patent infringement by Defendants of U.S. Patent No. 6,582,408 ("the '408 Patent") pursuant to 35 U.S.C. §§ 271 and 281-285 based upon the manufacture, use, sale, offer to sell and importation into the United States of Defendants' OptiClik® insulin pen device. (D.I. 1.)

On October 11, 2005, Defendants answered the Complaint by denying the infringement allegations and asserting counterclaims seeking declarations of invalidity and noninfringement of the '408 Patent. (D.I. 8.) Novo Nordisk answered Defendants' counterclaims on October 31, 2005. (D.I. 12.) Defendants amended their Answer and Counterclaims on September 8, 2006, which Novo Nordisk did not oppose. Defendants thereafter moved for leave to file a second Amended Answer and Counterclaim, which Novo Nordisk did oppose on grounds of prejudice. On April 12, 2007, the Court granted Defendants leave to file a second amended answer and counterclaims to include a counterclaim seeking a declaration of unenforceability of the '408 Patent. (D.I. 135.) Novo Nordisk filed its answer to Defendants' amended counterclaims on April 26, 2007. (D.I. 142.)

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¹ Novo Nordisk notes that, in October 2006, it withdrew a Complaint filed in an International Trade Commission ("ITC") investigation, in which it asserted a different, unrelated patent against sanofi-aventis based on the launch of OptiClik® in the United States. Inv. No. 337-TA-572.

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In its brief history the OptiClik® device has been beset by difficulties. On July 4, 2006, Ypsomed announced that it had “suspended” the production of OptiClik®. The suspension was to last a full eight (8) weeks, marking a significant lapse. (Vitola Decl. Ex. 1.)² Then, in an Announcement on September 14, 2006, Ypsomed formally acknowledged “production problems” with the OptiClik® device. (Vitola Decl. Ex. 2.) Also, on September 14, 2006, Ypsomed revealed the weak demand for sanofi-aventis’s infringing OptiClik® devices in the United States, noting that “sanofi-aventis has reduced orders and order forecasts for 2006/07 for insulin pens”. (*Id.*) Ypsomed also noted that “[t]he main reason given by sanofi-aventis for their reduced order forecast is a slower . . . uptake and overall weaker demand for the semi-disposable OptiClik® pen in the U.S. market . . .”, which they attributed to an assessment by sanofi-aventis of “a weaker demand, especially for the OptiClik® pen in the US market” (Vitola Decl. Exs. 2, 3.)³

² Citations to “Vitola Decl.” are to the accompanying Declaration of Stephen J. Vitola and exhibits thereto, which are being filed herewith.

³ See Ypsomed AG Conference Call, Sept. 14, 2006, http://www.ypsomed.com/en/medien_investoren/investoren/494.html

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⁴ Citations to “Green Decl.” are to the accompanying Declaration of Reza Green, Ph.D. which is being filed herewith.

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ARGUMENT

The exercise of judicial power under Article III of the U.S. Constitution requires the existence of a case or controversy. An actual controversy must exist at all stages of review, not

only at the time a complaint is filed. See Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1058 (Fed. Cir. 1995), cert. denied, 516 U.S. 1093 (1996) (quoting Preiser v. Newkirk, 422 U.S. 395, 401, 95 S.Ct. 2330, 2334, 45 L.Ed.2d 272 (1975)). Novo Nordisk's covenant not to sue removes any cause for concern that Defendants could be held liable for infringement of the '408 Patent. See Amana Refrigeration, Inc. v. Quadlux, Inc., 172 F.3d 852 (Fed. Cir. 1999); Super Sack, 57 F.3d at 1059; Spectronics Corp. v. H.B. Fuller Co., 940 F.2d 631 (Fed. Cir. 1991). Novo Nordisk's covenant not to sue has mooted any controversy between the parties. The Court therefore lacks subject matter jurisdiction over this action.

The existence of an actual case or controversy is an absolute jurisdictional prerequisite for declaratory judgments under 28 U.S.C. § 2201. See Super Sack, 57 F.3d at 1058 (citations omitted). As recently set forth by the U.S. Supreme Court, "the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." MedImmune, Inc. v. Genentech, Inc., 127 S.Ct. 764, 771 (2007), on remand to, 219 Fed. Appx. 986 (Fed. Cir. 2007) (citing Maryland Casualty Co. v. Pacific Coal & Oil Co., 312 U.S. 270, 273 (1941)). No subject matter jurisdiction exists over Defendants' counterclaims, which Novo Nordisk's covenant not to sue hereby moots. See Super Sack, 57 F.3d at 1059.

In Super Sack, the Federal Circuit affirmed the trial court's dismissal of the accused infringer's counterclaims of invalidity and non-infringement in view of Super Sack's promise not to assert the patents-in-suit against Chase as to any of Chase's past or present products. Super Sack, 57 F.3d at 1056-60. The Court found that this promise not to sue precluded the existence of a controversy between Super Sack and Chase as to the counterclaims. Id. The Federal Circuit

held that, although a defendant “may have some cause to fear an infringement under the [patents-in-suit] based on products that it may develop in the future,” a plaintiff’s covenant not to sue for any infringing acts involving products “made, sold, or used” on or before the date of the covenant is sufficient to divest a trial court of subject matter jurisdiction over a defendant’s declaratory judgment counterclaim. Id. at 1059. Like the promise not to sue in Super Sack, Novo Nordisk’s covenant not to sue has removed any cause for concern that Defendants could be held liable for infringement of the ‘408 Patent in connection with its accused OptiClik® insulin delivery devices. See id. Thus, there is no subject matter jurisdiction over this action, including Defendants’ counterclaims, and the action, including the counterclaims should be dismissed.

In accordance with the Federal Circuit’s precedent, this Court has consistently dismissed patent infringement actions in their entirety on the ground that a plaintiff’s covenant not to sue negated any actual controversy between parties and rendered the action moot. See e.g., Merck & Co., Inc. v. Apotex, Inc., C.A. No. 06-230 (GMS), 2007 WL 1470453 (D. Del. May 21, 2007); Merck & Co., Inc. v. Watson Laboratories, Inc., C.A. No. 05-658 (GMS), 2006 WL 1537375 (D. Del. June 2, 2006). For example, in Merck v. Apotex, decided only several weeks ago, this Court dismissed Merck’s patent infringement action, including Apotex’s counterclaims of invalidity and non-infringement, based on Merck’s covenant not to sue. Merck v. Apotex, 2007 WL 1470453, at *3-4. Merck originally asserted nine patents covering the drug alendronate sodium, which it marketed as FOSAMAX®, against Apotex in response to Apotex’s filing of an Abbreviated New Drug Application (“ANDA”) seeking regulatory approval to market a generic version of the drug. Id. at *2. Several months after filing the infringement suit, Merck granted Apotex a covenant not to sue upon receiving more detailed information from Apotex regarding its generic version of FOSAMAX. Id. In 2006, this Court similarly dismissed another patent

infringement suit brought by Merck against Watson, who had also filed an ANDA for regulatory approval of a generic form of FOSAMAX. Merck v. Watson, 2006 WL 1537375.

In Dow Chemical Co. v. Exxon Chemical Patents, Inc., Civ. A. No. 94-572-SLR, 1996 WL 571541 (D. Del. Sept. 20, 1996), plaintiff Dow Chemical sought a declaratory judgment in two counts. In the first count, Dow alleged that Exxon's patent was not infringed, was invalid and was unenforceable due to inequitable conduct. Dow Chemical, 1996 WL 571541, at *1. The second count was directed to state causes of action for unfair competition. Id. In response to Count 1, Exxon asserted counterclaims that Dow infringed the patent at issue. Id. Subsequently, after discovering the accused infringing product was performing poorly in the marketplace and thus did not warrant the expenditures associated with pursuing its infringement allegations, Exxon filed a statement of non-liability that released Dow from any potential liability for infringement of the patent at issue by the accused infringing product. Id. at *3. This Court concluded that Exxon's statement sufficiently protected Dow against any reasonable apprehension of suit, that Dow had not demonstrated an ongoing controversy regarding the patent at issue in light of Exxon's statement and, thus, no justiciable controversy existed. Id. This Court then dismissed Count 1 of Dow Chemical's declaratory judgment action in its entirety. Id.

Likewise, this Court, in Matsushita Battery Industrial Co., Ltd. v. Energy Conversion Devices, Inc., No. 96-101-SLR, 1997 WL 811563, at *2-7 (D. Del. Dec. 23, 1997), again dismissed a declaratory judgment action, including infringement counterclaims, for lack of subject matter jurisdiction after the patentee filed a motion to dismiss the action along with a "Covenant of Nonliability." Relying on Federal Circuit precedent, this Court found jurisdiction lacking because the patentee's statement of nonliability forever released the declaratory

judgment plaintiff from any claims of infringement of the patent-in-suit by certain of its existing batteries that could have formed the basis of an infringement suit. Id. at *6; See also Union Carbide Chem. & Plastics Tech. Corp. v. Shell Oil Co., 270 F. Supp. 2d 519, 523 (D. Del. 2003) (Robinson, Chief Judge) (dismissing defendants' counterclaims with respect to patents on which plaintiff filed a statement of non-liability because the statement, which is essentially a covenant not to sue, protects defendants from future litigation on those patents).

Given that Novo Nordisk has removed any actual controversy between the parties by providing to Defendants a covenant not to sue, all remaining issues are moot, and the Court is divested of subject matter jurisdiction over this action, including Defendants' declaratory judgment counterclaims. Accordingly, Novo Nordisk respectfully requests the Court dismiss the instant action and enter an order substantially similar to the form attached hereto as Exhibit B.

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Dated: July 5, 2007

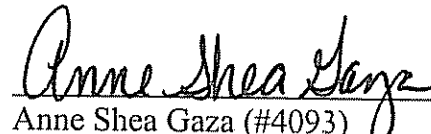
CERTIFICATE OF SERVICE

I hereby certify that on July 12, 2007, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following:

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I hereby certify that on July 12, 2007, I have sent by Federal Express the foregoing document to the following non-registered participants:

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